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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,543	07/25/2003	David Epstein	23239-537	3554

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,543	EPSTEIN ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/29/04, 07/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-7, in the reply filed on 04/22/2005 is acknowledged. Claims 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Status of the Application

Claims 1-7 are pending and currently under examination. Claims 8 and 9 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 broadly reads on any aptamer comprising a first binding domain that recognizes a first ligand and a second binding domain that recognizes a second binding

domain. Further claims 2-3 limit claim 1 by stating the first binding domain specifically interacts with an allosteric effector molecule, namely glucose, and the second ligand binding domain specifically interacts with any drug target of the allosteric effector molecule, namely an insulin receptor. Claims 4-7 further limit claim 1 by stating the binding of the second ligand by the second binding domain is activated or suppressed by the binding of the first ligand to the first binding domain.

The specification discloses general methods for generating an aptamer to a target of interest (see paragraph 0028-0091). The specification further discloses a method for generating neomycin regulated aptamer and discloses neomycin regulated aptamers that bind to an E. coli formamidopyrimidine glycosylase (Fpg) that is regulated by the presence of neomycin (see paragraph 0092-0097). Further the specification discloses a general method for preparing glucose regulated aptamers (see paragraph 00118-00122). The specification does not provide information regarding any structure of any aptamer that comprises a first binding domain that recognizes a first ligand and a second binding domain that recognizes a second binding domain wherein the first binding domain specifically interacts with an allosteric effector molecule, namely glucose, and the second ligand binding domain specifically interacts with any drug target of the allosteric effector molecule, namely an insulin receptor.

The scope of the claimed invention is so broad that the skilled artisan would not be able to envisage the entire genus claimed of aptamers targeted to any drug target that is regulated by any effector molecule and further the skilled artisan would not be able to recognize that the applicant was in possession of the claimed invention at the time of filing.

Moreover, the general knowledge in the prior art concerning regulatable aptamers does not provide any indication of what structure of what aptamer targeted to any target gene that would be regulated by any effector molecule.

MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")

Thus, the instantly claimed invention cannot be said to have been adequately described in a way that would convey with reasonable clarity to those skilled in the art that, as of the filling date sought, applicant was in possession of the claimed invention because the specification, while providing information on a neomycin regulated aptamer, does not provide any other information or guidance as to what structure of what aptamer, targeted to any target gene, that would be regulated by any effector molecule.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "[a]n aptamer comprising a first binding domain which recognizes a first ligand coupled to a second binding domain which recognizes a second ligand...."The claim implies there are two structures wherein the first structure consists of a first binding domain that recognizes a first ligand that is coupled to a second binding domain. Furthermore the term "coupled" is not defined in the specification and therefore it is unclear how the first ligand is coupled to the second binding domain.

Claims 6 and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 recites the limitation "wherein binding of the second ligand" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Soukup et al. (TIBTECH 1999, Vol. 17: 469-476).

Claim 1 discloses an aptamer comprising a first binding domain that recognizes a first ligand and a second binding domain that recognizes a second binding domain. Further claim 2 limits claim 1 by stating the first binding domain specifically interacts with an allosteric effector molecule and the second ligand binding domain specifically interacts with any drug target of the allosteric effector molecule. Claims 4-7 further limit claim 1 by stating the binding of the second ligand by the second binding domain is activated or suppressed by the binding of the first ligand to the first binding domain.

Soukup et al. teach an aptamer structure that comprises a first binding domain that recognizes a first ligand and further comprises a second binding domain that recognizes a second ligand (see Figure 1, page 470). Soukup et al. further teach the binding of the second domain is activated or suppressed by the binding of the first ligand to the first binding domain (see Figure 1, page 470) and further teach the aptamer structure is useful as an effector-dependent molecule to modulate biological processes associated with the effector molecule (see page 475, column 1).

Thus, Soukup et al. anticipates claims 1-2 and 4-7 of the instant application.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al. (Nucleic Acids Research 1998, Vol. 26, No. 18 : 4214-4221).

Claim 1 discloses an aptamer comprising a first binding domain that recognizes a first ligand and a second binding domain that recognizes a second binding domain. Further claim 2 limits claim 1 by stating the first binding domain specifically interacts with an allosteric effector molecule and the second ligand binding domain specifically interacts with any drug target of the allosteric effector molecule. Claims 4-7 further limit claim 1 by stating the binding of the second ligand by the second binding domain is activated or suppressed by the binding of the first ligand to the first binding domain.

Tang et al. teach an aptamer structure that comprises a first binding domain that recognizes a first ligand and comprises a second binding domain that recognizes a second ligand (see Figure 1, page 4216). Tang et al. further teach the binding of the second domain can be modulated by the binding of the effector molecule to the first binding domain (see page 4220).

Thus, Tang et al. anticipates claims 1-2 and 4-7 of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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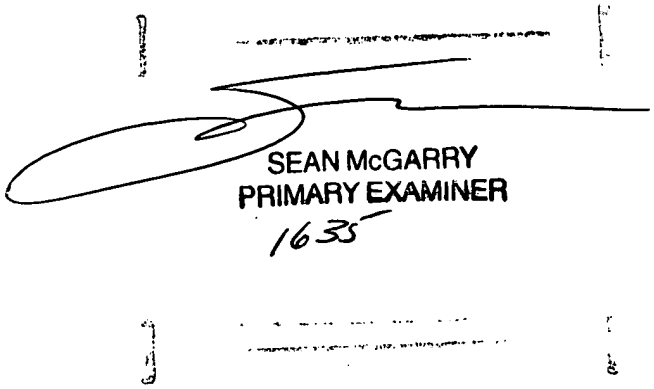

Kimberly Chong
Examiner
Art Unit 1635